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Remarks:

Amendments to the claims:

Claims 1-18 are pending in this application. By this Amendment, claims 5, 6, 13, 16 and 17 are amended to address a rejection under 35 USC 112.

No new matter is added to the application by this Amendment.

Regarding the rejections of claims 5-10, 13 and 16-18 under 35 USC 112, first paragraph:

The Patent Office alleges that claims 5-10, 13 and 16-18 are rejected as allegedly failing to comply with the written description requirement. Applicants respectfully disagree.

The Patent Office alleges that Applicants did not have possession of the claimed invention because the term "consisting essentially" is inadequately described by the instant specification, since it fails to contemplate the exclusion of any particular ingredients as implied therein; nor does it provide any criteria for determining if a given ingredient "materially affects the basic or novel characteristics of the invention. Applicants respectfully disagree with the allegations of the Patent Office.

Claims 5, 6, 13, 16 and 17 were amended to remove the term "essentially" from the claims. Applicants submit that the present claims comply with the written description requirement.

In view of the foregoing, Applicants respectfully request withdrawal of the rejection to the claims under 35 USC 112, first paragraph.

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Regarding the rejection of claim 1-18 under 35 USC 103(a) as allegedly being unpatentable over WO 99/13734 to Wolf (hereinafter "WO 734") in view of H&R, Frescolat Cooling Ingredients, 1999 (hereinafter "H&R"):

Applicants respectfully traverse the rejection of the foregoing claims in view of WO 734 and H&R.

Prior to discussing the merits of the Examiner's position, the undersigned reminds the Examiner that the determination of obviousness under 103(a) requires consideration of the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1 [148 USPQ 459] (1966): (1) the scope and content of the prior art; (2) the differences between the claims and the prior art; (3) the level of ordinary skill in the pertinent art; and (4) secondary considerations, if any, of nonobviousness. *McNeil-PPC, Inc. v. L. Perrigo Co.*, 337 F.3d 1362, 1368, 67 USPQ2d 1649, 1653 (Fed. Cir. 2003). There must be some suggestion, teaching, or motivation arising from what the prior art would have taught a person of ordinary skill in the field of the invention to make the proposed changes to the reference. *In re Fine*, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988). But see also *KSR International Co. v. Teleflex Inc.*, 82 USPQ2D 1385 (U.S. 2007).

A methodology for the analysis of obviousness was set out in *In re Kotzab*, 217 F.3d 1365, 1369-70, 55 USPQ2d 1313, 1316-17 (Fed. Cir. 2000) A critical step in analyzing the patentability of claims pursuant to section 103(a) is casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field. Close adherence to this methodology is especially important in cases where the very ease with which the invention can be understood may prompt one "to fall victim to the insidious effect of a hindsight syndrome wherein that which only the invention taught is used against its teacher."

It must also be shown that one having ordinary skill in the art would reasonably have expected any proposed changes to a prior art reference would have been successful.

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Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 1207, 18 USPQ2d 1016, 1022 (Fed. Cir. 1991); In re O'Farrell, 853 F.2d 894, 903-04, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988); In re Clinton, 527 F.2d 1226, 1228, 188 USPQ 365, 367 (CCPA 1976). "Both the suggestion and the expectation of success must be founded in the prior art, not in the applicant's disclosure." In re Dow Chem. Co., 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988).

The Patent Office acknowledges that WO 734 does not disclose an example comprising WS-3 and menthyl lactate or that the menthyl lactate is first liquefied (see page 4 of the Office Action). The Patent Office introduces H&R as allegedly disclosing that menthyl lactate is Fresoclat ML. The Patent Office alleges that (a) although the references do not disclose an example of a solution comprising menthyl lactate and menthol carboxamide, the references suggest a composition comprising the two components, (b) it would have been obvious to one of ordinary skill in the art to have made the suggested solution by melting menthyl lactate before adding it to menthol carboxamide and a solvent motivated by the desire to use a method that is disclosed in the art and is suggested by the manufacturer of menthyl lactate, and (c) by using the method of the combined teaching, it is reasonable to conclude the limitation that the concentration of menthyl lactate is higher than menthyl lactate when dissolved in a solvent is met because the concentration is dependent on the melting step. Applicants respectfully disagree with these allegations by the Patent Office.

Contrary to the Patent Office's allegations, H&R fails to remedy the deficiencies of WO 734 because H&R only discloses two options for using Frescolat ML (menthyl lactate), which is solid, soluble in oil, whereby neither option teaches or suggests the presently claimed method. In the first option, H&R discloses that the menthyl lactate is melted at a temperature of around $50-60^{\circ}$ C resulting in a liquid, and that is subsequently added to emulsions at a temperature of around $40-45^{\circ}$ C. In the second option, H&R discloses that the menthyl lactate is dissolved in perfume oils, cosmetic oils or glycol solvents.

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Nowhere does H&R teach or suggest that the Frescolat ML is first melted and then the melted Frescolat ML is subsequently added to a solvent. The H&R clearly teaches away by specifically teaching the two above-identified independent options of use of Frescolat ML.

Furthermore, Applicants respectfully disagree with the Patent Office's allegations that the WO 734 and H&R suggest a composition comprising the two compounds, namely menthyl lactate and WS-3. Nowhere in WO 734 and H&R is there such a teaching or suggest that or even hint to a composition comprising menthyl lactate and menthol carboxamide (WS-3). Moreover, the Patent Office merely makes such allegation and does not cite to any specific passage in the cited references that teaches or suggests or even hints that a composition may comprise menthyl lactate and menthol carboxamide. If such combination is not even mentioned within the cited references, how can a composition comprising menthyl lactate and menthol carboxamide be taught or suggested by WO 734 and H&R, taken singly or in combination? Clearly, the cited references fail to teach or suggest a composition comprising the two compounds as alleged by the Patent Office.

WO 734 discloses <u>flavor</u> compositions comprising cooling agents and such cooling agents may be made into a solution before further sprayed onto a powder. The solution of WO 734 may comprise about 5% to 30% cooling agent (see page 25, lines 8 –18 of WO 734). As alleged by the Patent Office, higher concentration of the cooling agent may be achieved only if higher temperatures are used. However, effect is known to a skilled person, namely, that by increasing the temperature of the solvent, e.g. water, the amount of a salt soluble in water increases.

WO 734 discloses that water is generally used as the solvent (see page 25, lines 13 of WO 734). However, as seen in Chemical Book (see Enclosure), WS-3 is insoluble in water. Thus, in view of the fact that WS-3 is insoluble in water, Applicants submit that the

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general statement made on page 25 of WO 734 is not applicable for all cooling agents and thus can't be adapted to a specific embodiment as done by the Patent Office.

WO 734 only discloses that WS-3 and menthyl lactate are cooling agents and may be used in combination.

Applicants agree with the Patent Office that WO 734 and H&R fail to disclose steps of liquefying menthyl lactate and then combining the liquefied menthyl lactate with menthol carboxamide and a solvent. However, the presently claimed invention specifically requires the above-mentioned steps.

The presently claimed method is a novel and patentable method for providing a solution comprising a much higher amount of menthyl lactate than that achievable by dissolving menthyl lactate in a neat solvent. Such solution having a much higher amount of menthyl lactate is achievable by first melting menthyl lactate and then combining the liquefied menthyl lactate with WS-3 and a solvent. Applicants further point out to the Patent Office that the presently claimed solution prepared from the method of claim 1 is characterized in that the final concentration of menthyl lactate is higher than that achievable by dissolving the menthyl lactate alone in a solvent.

WO 734 and H&R, taken singly or in combination, fail to teach or suggest a method of preparing a solution of menthyl lactate, wherein the final concentration of menthyl lactate is higher than that achievable by dissolving menthyl lactate in a neat solvent, by liquefying menthyl lactate and combining the liquefied menthyl lactate with menthol carboxamide and the solvent as required by claims 1, 5 and 11. Further, WO 734 and H&R, taken singly or in combination, fail to teach or suggest a solution consisting of menthyl lactate and menthol carboxamide dissolved in a solvent, characterized in that the final concentration of menthyl lactate is higher than that achievable by dissolving menthyl lactate alone in the solvent as required by claim 6.

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Still further, WO 734 and H&R, taken singly or in combination, fail to teach or suggest a method of improving the solubility of menthyl lactate comprising the steps of liquefying menthyl lactate and combining the liquefied menthyl lactate with menthol carboxamide and the solvent as required by claim 12. Moreover, WO 734 and H&R, taken singly or in combination, fail to teach or suggest a solution consisting of menthyl lactate and menthol carboxamide dissolved in a solvent as required by claim 13.

Because the features of independent claims 1, 5, 6 and 11-13 are not taught or suggested by WO 734 and H&R, taken singly or in combination, these references would not have rendered the features of independent claims 1, 5, 6 and 11-13 and their dependent claims obvious to one of ordinary skill in the art.

In view of the foregoing, reconsideration and withdrawal of this rejection are respectfully requested.

Regarding the provisional rejection of claims 1-18 under the doctrine of obviousness-type double patent as being unpatentable over (a) claim 16 and 22 of US Patent No. 7,414,152 (hereinafter "the 152 patent") in view of WO 734 and H&R; (b) claim 17 of copending Application No. 12/090801 (hereinafter "the 801 application") in view of WO 734 and H&R, (c) claim 12 of copending Application No. 12/282349 (hereinafter "the 349 application") in view of WO 734 and H&R, and (d) claim 15 of copending Application No. 11/1990561 (hereinafter "the 561 application") in view of WO 734 and H&R:

Applicants respectfully traverse the rejections of the claims 1-18 in view of (a) claims 16 and 22 of the 152 patent, (b) claim 17 of the 801 application, (c) claim 12 of the 349 application, and (d) claim 15 of the 561 application in view of WO 734 and H&R.

The Patent Office alleges that the combination of (a) claims 16 and 22 of the 152 patent, (b) claim 17 of the 801 application, (c) claim 12 of the 349 application, and (d) claim 15 of the 561 application with WO 734 and H&R teaches or suggests each and every feature

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recited in claims 1-18. Applicants respectfully disagree with the allegations by the Patent Office.

The arguments as set forth above with respect to the rejection under 35 USC 103 apply mutate mutandis and are also submit hereto in response to the above-mentioned provisional rejections of claims 1-18 under the doctrine of obviousness-type double patent. Moreover, WO 734, H&R, the 152 patent, the 801 application, the 349 application and the 561 application are, at best, directed to simple combinations of cooling agents only. In contrast, independent claims 1, 5, 6 and 11-13 are not directed to a simple combination of two cooling agents as discussed above with respect to the rejection under 35 USC 103. None of WO 734, H&R, claims 16 and 22 of the 152 patent, claim 17 of the 801 application, claim 12 of the 349 application, and claim 15 of the 561 application teach or suggest the steps liquefying menthyl lactate and then combining the liquefied menthyl lactate with menthol carboxamide and a solvent as required by the present claims.

WO 734, H&R, claims 16 and 22 of the 152 patent, claim 17 of the 801 application, claim 12 of the 349 application, and claim 15 of the 561 application, taken singly or in combination, fail to teach or suggest a method of preparing a solution of menthyl lactate, wherein the final concentration of menthyl lactate is higher than that achievable by dissolving menthyl lactate in a neat solvent, by liquefying menthyl lactate and combining the liquefied menthyl lactate with menthol carboxamide and the solvent as required by claims 1, 5 and 11. Further, WO 734, H&R, claims 16 and 22 of the 152 patent, claim 17 of the 801 application, claim 12 of the 349 application, and claim 15 of the 561 application, taken singly or in combination, fail to teach or suggest a solution consisting of menthyl lactate and menthol carboxamide dissolved in a solvent, characterized in that the final concentration of menthyl lactate is higher than that achievable by dissolving menthyl lactate alone in the solvent as required by claim 6.

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Still further, WO 734, H&R, claims 16 and 22 of the 152 patent, claim 17 of the 801 application, claim 12 of the 349 application, and claim 15 of the 561 application, taken singly or in combination, fail to teach or suggest a method of improving the solubility of menthyl lactate comprising the steps of liquefying menthyl lactate and combining the liquefied menthyl lactate with menthol carboxamide and the solvent as required by claim 12. Moreover, WO 734, H&R, claims 16 and 22 of the 152 patent, claim 17 of the 801 application, claim 12 of the 349 application, and claim 15 of the 561 application, taken singly or in combination, fail to teach or suggest a solution consisting of menthyl lactate and menthol carboxamide dissolved in a solvent as required by claim 13.

Because WO 734, H&R, claims 16 and 22 of the 152 patent, claim 17 of the 801 application, claim 12 of the 349 application, and claim 15 of the 561 application, taken singly or in combination, fail to teach or suggest each and every feature as claimed, the present claims are patentably distinct over WO 734, H&R, claims 16 and 22 of the 152 patent, claim 17 of the 801 application, claim 12 of the 349 application, and claim 15 of the 561 application. Accordingly, withdrawal of the obviousness-type double patenting rejection is respectfully requested.

Should the Examiner in charge of this application believe that telephonic communication with the undersigned would meaningfully advance the prosecution of this application, they are invited to call the undersigned at their earliest convenience.

The early issuance of a *Notice of Allowability* is solicited.

PETITION FOR A ONE-MONTH EXTENSION OF TIME

Applicants respectfully petition for a one-month extension of time in order to permit for the timely entry of this response. The Commissioner is hereby authorized to charge the fee to Deposit Account No. 14-1263 with respect to this petition.

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CONDITIONAL AUTHORIZATION FOR FEES

Should any further fee be required by the Commissioner in order to permit the timely entry of this paper, the Commissioner is authorized to charge any such fee to Deposit Account No. 14-1263.

Respectfully Submitted;

Reg.No. 32,431

Norris, McLaughlin & Marcus P.A.

875 Third Avenue

New York, NY 10017

19 .

Enclosure -- N-ethyl-p-menthane-3-carboxamide (ex. "Chemical Book")

CERTIFICATION OF TELEFAX TRANSMISSION:

I hereby certify that this paper and any indicated enclosures thereto is being telefax transmitted to the US Patent and Trademark Office to telefax number: 571-273-8300 on the date shown below:

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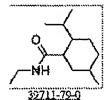
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N-Ethyl-p-menthane-3-carboxamide

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N-Ethyl-p-menthane-3-carboxamide Product Description



CAS Na

39711-79-0

Chemical Name: Synonyms:

N-Ethyl-p-menthane-3-carboxamide FEMA 3455;WS-3;n-ethyl-5-methyl-2-(1-methylethyl)-

cyclohexanecarboxamid; TIMTEC-BB SBB008527; N-ETHYL-5-METHYL-2-(1-METHYLETHYL)-CYCLOHEXANE-CARBOXAMIDE;N-ETHYL-5-METHYL-2-(1-METHYLETHYL)-CYCLOHEXANE-CARBOXYAMIDE;N-ETHYL 5-METHYL-2-ISO-PROPYLCYCLOHEXANECARBOXAMIDE;N-ETHYL-4-MENTHANE-3-CARBOXAMIDE;N-ETHYL-2-ISOPROPYL-5-METHYLCYCLOHEXANE CARBOXAMIDE;N-ETHYL-P-MENTHAN 3-CARBOXAMIDE;N-ETHYL-P-

MENTHANE-3-CARBOXAMIDE: ETHYL MENTHANE

CARBOXAMIDE;MENTHANE CARBOXAMIDE;N-Ethyl-hexahydro-p-cymene-3carboxamide; Cyclohexanecarboxamide, N-ethyl-5-methyl-2-(1-methylethyl)-; N-ETHYL-PARA-MENTHANE-3-CARBOXAMIDE;N-Ethyl-2-(isopropyl)-5methylcyclohexancarboxamid;N-Ethyl-p-methane-3-carboxamide, Ethyl menthane carboxamide, Framidice 3, Menthol Carboxamide WS-3; Menthol Carboxamide WS-3; N-Ethyl-5-methyl-2-propan-2-ylcyclohexane-1-carboxamide

CBNumber:

CB0252522

Molecular .

C13H25NO

Formula:

Formula Weight:

211.34

MOL File:

39711-79-0-mel

V-Ethyl-p-menthane-3-carboxamide Property

mp:

87-102 °C

FEMA:

3455

Water Solubility:

insoluble

CAS DataBase Reference:

39711-79-0(CAS DataBase Reference)

KPA Substance Registry

System:

39711-79-0(EPA Substance)

Safety

Hazard Codes:

<u>XiXn</u>

Wick Statements:

36-41-22

Sufriy Statements:

35-25

N-Ethyl-p-menthane-3-carboxamide Chemical Properties, Usage, Production

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3)) Pharmschem international (Wuhsu) Co.,Ltd.	86-027-87785560 027- 87785546-8082	86-027- 87526527	huatery	¥u@3h&c,⇔m	CHINA	<u>4308</u>	3.5
J & K Chamical Limited	86-10-82848833	861082849933	jkinfo@j	kebenical.com	CRINA	<u> 28775</u>	70

9711-79-0(N-Ethyl-p-menthano-3-carboxamido)Related Search:

Methylparaban Formamide Methyl scetate Krasokim-mathyl Ethyl scrylate Ethyl formate Ethylparaban Cyclohexane

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PEMA 3455-3971 1-79-0 WS-3 n-ethyl-5-methyl-2-(1-methylethyl)-cyclohexanccestionaemid TIMTEC-BB SBB008527 N-ETHYL-5-METHYL-2-(1-METHYL-ETHYL)-CYCLOHEXANE-CARBOXAMIDE N-ETHYL-5-METHYL-2-METHYL-2-(1-METHYL-ETHYL)-CYCLOHEXANE-CARBOXAMIDE N-ETHYL-4-MENTHANE-3-CARBOXAMIDE N-ETHYL-2-ISOPROPYL-5-METHYL-CYCLOHEXANE-CARBOXAMIDE N-ETHYL-4-MENTHANE-3-CARBOXAMIDE N-ETHYL-2-ISOPROPYL-5-METHYL-CYCLOHEXANE-CARBOXAMIDE N-ETHYL-P-MENTHANE-3-CARBOXAMIDE SETHYL MENTHANE CARBOXAMIDE MENTHANE-3-CARBOXAMIDE N-ETHYL-P-MENTHANE-3-CARBOXAMIDE SETHYL MENTHANE CARBOXAMIDE MENTHANE CARBOXAMIDE N-Ethyl-boxahydro-p-cymene-3-carboxamide Cyclohexanccarboxamide, N-ethyl-5-methyl-2-(1-methyl-ghyl)-N-ETHYL-PARA-MENTHANE-3-CARBOXAMIDE N-Ethyl-2-(isopropyi)-S-methyl-cyclohexancarboxamid N-Ethyl-p-nethyl-2-fixepropyi)-S-methyl-gyclohexancarboxamid N-Ethyl-5-methyl-2-propan-2-ylcyclohexanc-1-carboxamide N-Ethyl-2-isopropyi-S-methyl-cyclohexancarboxamide WS-3 N-Ethyl-5-methyl-2-propan-2-ylcyclohexanc-1-carboxamide N-Ethyl-2-isopropyi-S-methyl-cyclohexanc-1-carboxamide

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Filing Date

STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)			First N	First Named Inventor Christ			hristope GALOPIN				
			Art Un	Art Unit			1612				
			Exam	Examiner Name		Leza	ezah ROBERTS				
·				Attorn	Attorney Docket Numb		er	102790-131(30070 US)			
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INFORMATION DISCLOSURE	First Named Inventor Christ		stope GALOPIN		
STATEMENT BY APPLICANT	Art Unit		1612		
(Not for submission under 37 CFR 1.99)	Examiner Name	Lezah ROBERTS			
	Attorney Docket Number		102790-131(30070 US)		
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	Filing Date		2005-04-25		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)	First Named Inventor Christope GALOPIN				
	Art Unit		1612		
(Not for submission under 37 CFK 1.99)	Examiner Name	Lezal	h ROBERTS		
	Attorney Docket Numb	er	102790-131(30070 US)		

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	That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).								
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\Box	See attached certification statement.								
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	Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.								
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Name/Print		Andrew N. Parfomak		Registration Number	32431				
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